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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,541

05/26/2006

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CHANG220

3244

1444 7590 04/22/2009  
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EXAMINER

SAKELARIS, SALLY A

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

04/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,541	<b>Applicant(s)</b> CHANG ET AL.	
	<b>Examiner</b> Sally A. Sakelaris	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/26/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12 and 35 drawn to a method for examining a blood type classified in Class 436, subclass 66.

Group II, claim(s) 13-34, drawn to a microfluidic device for analyzing blood as classified in Class 422, subclass 100.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I and II lack unity of invention because even though the inventions of these groups require the technical feature of examining blood through the use of a fluid handling system, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Wilding et al US Patent 5,635,358. Wilding et al teach a fluid handling method for use in mesoscale analytical devices that is taught to manipulate blood for various parameters.

During a telephone conversation with Mr. Sheridan Niemark on 3/18 and a provisional election was made with traverse to prosecute the invention of Group II, claims 13-34. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

Art Unit: 1797

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

Art Unit: 1797

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Specification***

The disclosure is objected to because of the following informalities: the reference characters "304" and "305" have both been used on page 14 of the specification to designate the base plate of the invention.

In line 22 of the specification the reagent storage chamber is referred to as "340" but elsewhere in the disclosure "340" describes the filter.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Art Unit: 1797

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 13-18, 22-29, and 32-34 are rejected under 35 U.S.C. 102(b) as being under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. (US Patent 5,635,358).

With regard to claim 13, Wilding et al teach:

A blood injecting chamber(Figure 7, 16A-D);  
plural micro-channels one end of which is connected to the blood injection chamber(Figure 7, 20A-C, etc);  
plural reagent storage chambers connected to the other end of the micro-channel (Figure 7, 22A-D);  
plural micro-filters connected with reagent storage chambers respectively (Fig. 8-10, (24)); and  
plural reading channels connected to the micro-filters respectively (Fig.7, 40).

With regard to claims 14-18, and 28 and 29 Wilding teach plural reading parts arranged in parallel (40), the filter chamber (22B or 28) with plural filter poles (26 or filter elements in 28) formed in the filter chamber, the width of the filter pole is longer than its

Art Unit: 1797

length in a cross sectional view (Fig. 7, 28) and the filter poles are allocated crossly to the direction of the fluid which passes through the microfilter (22B or 28), and a first blood resistance part (22B with 24) is formed between the storage chamber and the micro-filter.

With regard to claims 22-24 and 32-34 an inhaling hole is taught in any of (16A-D) at the end of the reading channel (40). Claims 23, 24 and 34 recite intended uses for the aforementioned device components above and will not be afforded patentable weight.

With regard to claim 25 and 26, a base plate is taught in Col. 3 line 41 wherein: "The chips typically will be used with an appliance which contains a nesting site for holding the chip". a chip plate (14), reading chambers (within 40) located on the reading channel (40) and form a transparent reading window(12).

With regard to claim 27, the chip plate is taught to be made from Teflon (Col. 5 line 54).

Generally, Wilding et al teach in their Table 1 that their invention has "no limits to the number of chip designs or applications available" (col.4) and in Figures 1 and 7 provide only examples of how their chips may be arranged. The plural reading channels for example, can be placed in varied locations on the chip as necessitated by the process at hand. Wilding et al. teach the placement of these plural reading channels to occur either upstream or downstream of the micro-filters (Fig. 1 and 7).

Wilding et al. do not teach the particular embodiment applicant has envisioned in a single example in their specification or in figures 1 or 7.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the various features taught by Wilding in the particular combination claimed by the applicant as Wilding teaches all of the features applicant is claiming and furthermore provides the motivation to vary these features as needed in his teaching that there are “no limits to the number of chip designs or applications available”. Also this flexibility in Wilding et al’s system is attractive as it allows for competitive pricing with existing systems and “expands the capabilities for assay and process monitoring to virtually any system, allowing for a broad range of applications”(Col. 4, Table 1).

2. Claims 19-21 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding in view of McNeely et al (US Patent 6296020).

Wilding et al's teachings can be viewed above.

Wilding et al. do not teach a first hydrophobic surface-processed part which is hydrophobic on the bottom of the first resistance channel, nor do they teach a second blood resistance part comprising a second hydrophobic surface processed part which is hydrophobic on the bottom of the reading channel.

McNeely et al teach the control of fluid flow through microchannels by use of stopping means in the microchannels (Fig. 2E -J). Fig. 2E illustrates the geometry and position of the stopped fluid if stopping means “a” were that of a hydrophobic restriction. (Col. 7 lines 32-37). Fig 2I illustrates the geometry and position of the stopped fluid if stopping means “a” were that of a hydrophobic patch (Col 7 line 44).



Art Unit: 1797

It would have been obvious to insert McNeely's hydrophobic patches to the bottom's of resistance channel and to the reading channels of Wilding et al for the because "well planned use of stopping means acting as passive valves allows the flow of fluids through micro-channels to be regulated so as to allow fluids to be mixed or diluted after being introduced via a single channel" (Abstract).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 5712726297. The examiner can normally be reached on Monday-Friday 8-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 5712721267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sally Sakelaris

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797